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EXAMINER	
OU, JING RUI	

ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
09/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/809,194	LIPOMA ET AL.	
	Examiner	Art Unit	
	JING OU	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-29 and 31-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-29 and 31-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/29/2008, 06/12/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is responsive to the amendment filed on June 12, 2008. Claims 26-29 and 31-45 are pending. Claims 26 and 42 are independent. Claims 37-45 are newly added. Claims 1-25 and 30 are cancelled.

Double Patenting

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Applicant is advised that should claims 39 and 45 be found allowable, claims 39 and 45 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

4. Claims 26-29 and 31-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

was filed, had possession of the claimed invention. Support for the limitations "only a stimulating site that is laterally adjacent the puncture site" and "the lancing travel paths and the stimulating travel path are side-by-side, parallel, and non-coaxial" in Claims 26 and 42, and "they travel substantially the same distance" in Claims 41 and 42 cannot be found in the original disclosure and are considered as new matter. Applicant should be noted that the longitudinal cross-section view of the lancing device as shown in Figure 63 is not sufficient to support these limitations.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 26-28 and 31-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Verdonk et al (US Pat. No.: 6,306,152).

In regard to Claims 26-28 and 31-45, Verdonk et al discloses a housing (**164**, Fig. 5) defining a lancing opening (**opening of 164 at which 200 moves through**, Figs. 5 and 9) and a stimulating opening (**opening of 164 at which 138 moves through**, Figs. 5) in a side-by-side arrangement; a lancet (**104**, Fig. 5) having puncturing tip (**138**); an elongated stimulator member (**combination of one of the 200 and 202**) having an impacting portion (**200**), wherein the stimulator member travels along a stimulating travel path toward an extended position with the stimulating portion extending out of the housing to impact the skin at only a stimulating site (one of the 200 impacts the skill at

only a stimulating site) that is laterally adjacent the puncture site to create a sensory distraction adjacent the at only the stimulating site laterally adjacent the puncture site before or simultaneously with the puncturing of the skin (Figs. 5 and 9 and Col. 6, lines 52-67 and Col. 7, lines 1-18); wherein the stimulator member and the lancet are in a side-by-side arrangement so that the lancing travel path and the stimulating travel path are side-by-side, parallel, and non-coaxial (As seem in Fig. 9, when replacing 152 with 202, the lancing travel path and the stimulating travel path are side-by-side, parallel, and non-coaxial); and wherein the stimulator member impacting portion is defined by a blunt tip (the bottom tip or end of the skin stabilizer is blunt, Fig. 9); a single drive spring (**168**, Fig. 5) for driving both the simulator member and the lancet (col. 6, lines 58-67 and col. 7, lines 1-13); a single drive member (base plate, **162**, Fig. 5) that is driven by the single drive spring and that in turn drives the stimulator and the lancet (Col. 6, lines 25-67 and col. 7, lines 1-13) so they travel substantially the same distance (Figs. 5 and 9); wherein the stimulator member has a drive surface (the top surface of 200 of the skin stabilizer that contacts the bottom surface of the base plate, Fig. 9) and the lancet has a drive surface (the top surface of the lancet that contacts the bottom surface of the base plate, Fig. 5), and wherein the drive member has a contact surface that engages the drive surfaces of the stimulator member and the lancet to drive forward both the stimulator member and the lancet (Figs. 5 and 9); wherein the stimulator drive surface and the lancet drive surface are generally laterally aligned (Figs. 5 and 9), and wherein the drive member contact surface is generally flat (Fig. 5); wherein the stimulator is longer than the lancet (Figs. 5 and 9); and wherein the lancet and the stimulator are

arranged according to a varied length scheme for timing the puncturing simultaneously with or after the stimulator impact (Col. 6, lines 36-44 and Col. 2, lines 59-66).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Verdonk et al (US Pat. No.: 6,306,152) in view of Burns (US Pat. No.: 4,527,561).

Verdonk et al discloses the device further comprising a drive spring (**168**, Fig. 5) as taught above but fails to disclose two other separate springs including a stimulator return spring and a lancet return spring.

However, Burns explicitly teaches a lancet return spring (**28**, Fig. 8) that retracts the lancet tip from the extended position back into the housing (Col. 2, lines 33-36).

Verdonk et al and Burns are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teaching of Verdonk et al and Burns before him or her, to modify the lancing device of Verdonk et al to include a lancet return spring as taught by Burns and to include a stimulator return spring similar to the lancet return spring as taught by Burns.

The suggestion/motivation for having a lancet return spring would have been to automatically retract the lancet back into the housing (Burns, Col. 2, lines 29-36) and to maintain the lancet in position (Burns, Col. 4, lines 50-51). The suggestion/motivation for having a stimulator return spring similar to the lancet return spring as taught by Burns would have been to automatically retract the stimulator member back to original position inside the housing.

Therefore, it would have been obvious to combine Burns with Verdonk et al to obtain the invention as specified in the instant claim.

Response to Arguments

11. Previous objection to the drawings has been overcome.

12. Applicant's arguments filed 06/12/2008 have been fully considered but they are not persuasive. Regarding the argument on page 11 of the remarks Verdonk et al discloses an elongated stimulator member (**combination of one of the 200 and 202**) having an impacting portion (**200**), wherein the stimulator member travels along a stimulating travel path toward an extended position with the stimulating portion extending out of the housing to impact the skin at only a stimulating site (one of the 200 impacts the skill at only a stimulating site) that is laterally adjacent the puncture site to create a sensory distraction adjacent the at only the stimulating site laterally adjacent the puncture site before or simultaneously with the puncturing of the skin (Figs. 5 and 9 and Col. 6, lines 52-67 and Col. 7, lines 1-18); and wherein the stimulator member and the lancet are in a side-by-side arrangement so that the lancing travel path and the stimulating travel path are side-by-side, parallel, and non-coaxial (As seem in Fig. 9, when replacing 152 with 202, the lancing travel path and the stimulating travel path are side-by-side, parallel, and non-coaxial).

Regarding the argument on Claim 29 on page 11 of the remarks, Verdonk et al discloses the device further comprises a drive spring (**168**, Fig. 5) as taught above but fails to disclose two other separate springs including a stimulator return spring and a lancet return spring. However, Burns explicitly teaches a lancet return spring (**28**, Fig. 8) that retracts the lancet tip from the extended position back into the housing (Col. 2, lines 33-36). Verdonk et al and Burns are analogous art because they are from the

same field of endeavor. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teaching of Verdonk et al and Burns before him or her, to modify the lancing device of Verdonk et al to include a lancet return spring as taught by Burns and to include a stimulator return spring similar to the lancet return spring as taught by Burns. The suggestion/motivation for having a lancet return spring would have been to automatically retract the lancet back into the housing (Burns, Col. 2, lines 29-36) and to maintain the lancet in position (Burns, Col. 4, lines 50-51). The suggestion/motivation for having a stimulator return spring similar to the lancet return spring as taught by Burns would have been to automatically retract the stimulator member back to original position inside the housing. Therefore, it would have been obvious to combine Burns with Verdonk et al to obtain the invention as specified in the instant claim.

Regarding the argument on page 12 of the remarks, the embodiment of the device comprises legs 200 as shown in Fig. 9 in Verdonk et al. The length of combination barrel 202 and the legs 200 would be longer than the length of the lancet.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JO

/Julian W. Woo/
Primary Examiner, Art Unit 3773

September 8, 2008